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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,631	12/05/2003	John F. Shanley	032304-088	1114

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CINDY A. LYNCH
CONOR MEDSYSTEMS, INC.
1003 HAMILTON COURT
MENLO PARK, CA 94025

EXAMINER	
BLANCO, JAVIER G	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,631	SHANLEY ET AL.	
	Examiner	Art Unit	
	Javier G. Blanco	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-83* is/are pending in the application.

4a) Of the above claim(s) *54,55,62,67-73,79 and 80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-53,56-61,63-66,74-78 and 81-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *09/07/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Applicants' cancellation of claims 1-48 in the reply filed on September 13, 2004 is acknowledged.

2. Applicants' addition of claims 49-83 in the reply filed on September 13, 2004 is acknowledged.

Election/Restrictions

3 Applicants' election of **Device**: Species B (Figure 3); **Openings**: Species A (Figure 14); **Thickness of openings**: Species A (through openings); **"Shape" of therapeutical substance**: Species A (Figure 9: discrete layers); **Therapeutic substance**: Species A (chemically ablative agent); **Beneficial agent**: Species A (paclitaxel); **Plurality of beneficial agent layers**: Species A (layers of different chemical compositions); and **Systemically applied agent**: Species A (ultrasound) in the reply filed on September 7, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

4. Claim 62 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 7, 2004.

Supplemental Election/Restriction

5. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 49-66 and 74-83, drawn to an expandable medical device comprising a beneficial agent(s), classified in class 623, subclass 1.42.

II. Claims 67-73, drawn to a method of forming an expandable medical device, classified in class 623, subclass 1.15.

The inventions are distinct, each from the other because of the following reasons:

6. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process that does not require evaporation of a solvent. For example, the drug(s) + polymeric carrier could be contained within liposomes, then loaded within the plurality of openings. Another possibility, the stent could be coated with a drug(s) + polymeric carrier solution, then the excess solution could be wipe out, leaving the drug(s) + polymeric carrier inside the plurality of openings.

7. Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

8. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species A: First and second agents are delivered to a mural side of the stent

Species B: First agent is delivered to a mural side of the stent; second agent is delivered to a luminal side of the stent

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

9. During a telephone conversation (e-mail message) with Mrs. Cindy Lynch on October 26, 2004 a provisional election was made without traverse to prosecute the invention of Group I (claims 49-66 and 74-83) and Species A (first and second agents are delivered to a mural side of the stent). Affirmation of this election must be made by applicant in replying to this Office action. Claims 54, 55, 62, 79, and 80 (Election of Species Requirement), and 67-73 (Restriction

Requirement) are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention/species.

Claim Objections

10. Claims 59 and 65 are objected to because of the following informalities:

a. Regarding claim 59, please substitute "to a first side" (see line 7) with --to a second side--. Appropriate correction is required.

b. Regarding claim 65, please substitute "layers" (see line 1) with --layer--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 49-53, 56, 57, 59-61, 63-66, 74-78, 81, and 82 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Burkoth et al. (WO 98/23228 A1; cited in Applicants' IDS).

As seen in Figures 3-11, 17, and 18, Burkoth et al. discloses a directional drug delivery stent (e.g., either stent 11 or stent 111) comprising:

a. A plurality of struts (see Figures 17 and 18),

b. A plurality of holes or openings (e.g., Figures 3-10: cavity 20 and/or opening 22; Figures 6 and 8: holes 28, 54; Figure 18: spaced apart groove portions 114). The holes/openings could be through holes/openings (e.g., see through holes/openings shown in Figures 7, 8, and 10) or partially through holes/openings (see page 8, line 30 to page 9, line 5; page 19, line 6 to page 20, line 10; see entire document). The holes/openings may be directly filled with the active agent/drug (see page 19, lines 3-5; see entire document),

c. At least one beneficial agent (e.g., Figures 3-11, 17, and 18: beneficial agents 23, 25). These agents are either **(i)** the same agent (i.e., an anti-proliferative, or, an anti-inflammatory, or, a protein drug), or, **(ii)** different agents (i.e., an anti-proliferative and an anti-inflammatory; see page 7, lines 1-29; page 16, lines 17-18; see entire document), the agent(s) is arranged to be delivered to a mural side (or to a luminal side) of the stent (see page 9, lines 6-26),

d. A carrier (e.g., Figure 4: biodegradable polymeric delivery matrix 27; see page 13, lines 3-14; see entire document), and

e. A barrier (e.g., Figure 5: biodegradable membrane 34; see page 13, lines 15-23; Figure 10: separating membrane 49; see page 16, lines 19-31; see entire document). Biodegradable membrane 34 provides a desired diffusional delivery rate of active agent 23 (see page 13, lines 18-19). As shown in Figure 10, cavity 20 shows a layer of beneficial agent 23 separated from a layer of beneficial agent 25 by separating membrane 49 (= barrier layer). Depending on the particular drug/agent used (i.e., an anti-proliferative, or, an anti-inflammatory, or, a protein drug) and the predetermined location (mural and/or luminal side), each drug will have a different release profile (see entire document).

13. Claims 49-53, 56-61, 63-66, 74-78, and 81-83 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Santini, Jr. et al. (US 6,656,162; cited in Applicants' IDS).

As seen in Figures 1, 2A-2E, 9A, and 9C, Santini, Jr. et al. disclose an expandable medical device comprising (i) a substantially cylindrical expandable medical device formed of a plurality of struts (see Figures 9A and 9C; see column 10, lines 44-67; column 14, line 63 to column 15, line 23), (ii) a plurality of openings (i.e., reservoirs) in the plurality of struts (see Figures 9A and 9C; see column 10, lines 44-67; column 14, line 63 to column 15, line 23), and (iii) a plurality of beneficial agent layers (i.e., an anti-proliferative, or, an anti-inflammatory, or, a protein drug: either in "pure form" or embedded in a biodegradable polymeric matrix) formed in the openings, wherein the plurality of beneficial agent layers (see column 5, lines 30-33) include a first active agent arranged for delivery according to a first release profile (e.g., Figure 2d, agent 540a; see column 4, lines 33-62; column 5, lines 20-37) and a second active agent arranged for delivery according to a second release profile (e.g., Figure 2d, agent 540b; see column 4, lines 33-62; column 5, lines 20-37). A barrier layer (reservoir cap and/or backing plate) is formed within the openings to block or retard delivery of the first and second active agents to the luminal side of the device body (see entire document).

Conclusion

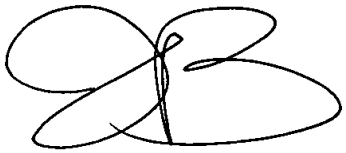
14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Maruyama et al. (US 5,017,381 A).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:30 a.m.-4:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned is 703-872-9306 for regular communications and After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

JGB



October 26, 2004

David H. Willse
Primary Examiner